JUDGE ROBERT J. BRYAN

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

UNITED STATES OF AMERICA, Plaintiff, v. RICHARD MARSCHALL, Defendant.	No. CR20-5270RJB REPLY TO GOVERNMENT'S RESPONSE (DKT. 57) TO MOTION TO DISMISS

I. Introduction

The government essentially claims, in its response, that the Dietary Health and Education Act (DSHEA) of 1994 has no effect or impact in Mr. Marschall's case. The government applied a similar approach with its presentation to the grand jury when it secured an indictment in this case. Since the filing of this motion to dismiss (Dkt. 45), the government has disclosed a copy of the grand jury transcripts and a copy of an exhibit presented to the grand jury in support of the indictment to Mr. Marschall. (Dkt. 60), (Grand Jury Transcript *under seal*). As revealed by grand juror questions, the grand jury was never legally instructed as to the applicability of the DSHEA to this case:

> GRAND JUROR: So, yes. Given that they're fairly clearly labeled as supplements, how do you get from I'm selling supplements to I'm selling something that needs a prescription? How is it that you determine that these together end up -- become prescription drugs? I've heard that. I heard you say it. Help me draw that line a little bit brighter, please…

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> A. It's really in the labeling as well, the intended use behind the labeling. The initial label that is on the bottles does not state that it cures COVID or anything along that line, but the additional document that Mr. Marschall provided with the – with the products, stating that it treats COVID, cures COVID, many other viruses and bacterias and infections, that right there is -- constitutes as labeling for the products. So when these articles are supposed to treat, cure, mitigate, or prevent a type of disease, they are now drugs. And then since COVID can't be self-diagnosed or self-treated, that makes it – a prescription drug is needed in order to cure that specific disease…
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> GRAND JUROR: I guess I'm also a little confused by the prescription aspect. There are -- there are conditions that I can't diagnose myself but I can treat with over-the-counter products. How does the FDCA definition of prescription drugs differentiate those?
>
> THE WITNESS: Prescription drugs would be a little bit different than a drug. You could have over-the-counter drugs that are considered like cough suppressants, Advil, those type of things, even allergy medications that you can go pick up and that are over the counter that are considered drugs. The other ones, as far as when it's trying to do any of these specific things: cure, treat, prevent, mitigate for a particular disease such as COVID, those then are to be under the supervision of a physician, and then they would provide a prescription for that.

Id., p. 14, 16-17.

It is important to remember the undisputed facts: the items shipped by Mr. Marschall were in fact dietary supplements; the items contained foods which have been deemed safe for human consumption by the FDA; and the government is not claiming that Mr. Marschall made false or misleading claims as to the Dynamic Duo's ability to prevent disease or promote health.

It is perfectly legal for Mr. Marschall to sell Allimax Pro (Allimed) and IAG arabinogalactans because they are both supplements that have been deemed safe for human consumption by the FDA. *See* 21 C.F.R. § 172.610 and 21 C.F.R. § 184.1317. It is perfectly legal for the manufacturers of these products to manufacture and introduce these items into interstate commerce.

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The government has initiated proceedings against Mr. Marschall under the wrong legal provision. 21 U.S.C. § 331 (Misbranded Drugs). Because this case involves foods, the applicable law is the misbranded foods provision. 21 U.S. Code § 343 (Misbranded Foods). For these reasons, reasons set out below, and reasons set out in his opening motion, Mr. Marschall respectfully asks that the Court dismiss the indictment pursuant to Federal Rule of Criminal Procedure 12(b)(3)(B)(v).

II. Mr. Marschall is not asking this Court to make a factual determination but rather a legal determination as to whether supplements that fall under the DSHEA or are a "food" under the Food, Drug, and Cosmetic Act (FDCA) that can transform into a "drug" based on a set of facts that are not disputed by the government.

A. A pretrial motion under Rule 12(b) is appropriate.

A district court's interpretation of a statute is a *de novo* determination, *United States v. Wilson*, 720 F.2d 608, 609 n.2 (9th Cir. 1983), as is a court's determination of the elements of an offense. *United States v. Douglass*, 780 F.2d 1472, 1475 (9th Cir. 1986).

Rule 12(b) permits consideration of any defense "which is capable of determination without the trial of the general issue." Fed. R. Crim. P. 12(b). A motion to dismiss is generally "capable of determination" before trial "if it involves questions of law rather than fact." *United States v. Shortt Accountancy Corp*., 785 F.2d 1448, 1452 (9th Cir. 1986), *cert. denied*, 478 U.S. 1007 (1986). Although a court may make preliminary findings of fact necessary to decide the legal questions presented by the motion, it may not "invade the province of the ultimate finder of fact." *Id*. at 1452; *also see United States v. Webb*, 166 F.Supp.3d 1198 (W.D. Wash. 2016) (dismiss Armed Career Criminal Allegation under Rule 12(b))(Lasnik, J.); *United States v. Casey*, 2020 WL 1940446 (W.D. Wash. 2020) (dismissing a count under Rule 12(b) after determining that a prior is not a habitual offense under 18 U.S.C. § 117(a)) (Jones, J.);

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United States v. Turner, 2007 WL 1300462 *4 (W.D. Wash. 2007) (Coughenour, J.) ("Where a possible…error can be avoided pre-trial, this Court finds that it ought to be, even if the Government would present the same evidence either way."); *United States v. Thompson*, 202 F. Supp. 503 (N.D.Cal.1962) (dismissing an indictment under Rule 12(b) after determining that a sawed-off shotgun without a firing pin was not a firearm within the National Firearms Act.); *United States v. Kaplan*, 836 F.3d 1199, 1216 (9th Cir. 2016) (suggesting that an indictment under 21 U.S.C. § 333(a)(2) that fails to allege materiality may be subject to dismissal in a pretrial motion).

The issue of whether the products shipped by Mr. Marschall to the undercover agent can be prosecuted as drugs under the FDA is purely a legal question that does not require preliminary findings of fact because none of the facts are disputed by the government. Mr. Marschall has presented detailed facts to this Court in two separate motions to dismiss. Dkt. 44 at 2-12 (Motion to Dismiss Indictment); Dkt. 45 at 1-3 (Motion to Dismiss Indictment). In both motions, he stated that "(i)f the government disputes any facts, it should specifically identify them for the purposes of an evidentiary hearing." Dkt. 44 at 2, fn. 2; Dkt. 45 at 1, fn. 1. In both responses, the government did not dispute any facts and stated that "(t)he motion to dismiss does not require an evidentiary hearing," Dkt. 56 at 2, fn. 2 (Government Response), Dkt. 57 at 2 (Government Response) ("An evidentiary hearing is not required.").

It would promote judicial economy to resolve this issue at this time because a legal determination in Mr. Marschall's favor would avoid the need for a trial. Given the COVID-19 outbreak and the current general order which prohibits trials at the courthouse, General Order No. 13-20, it would promote judicial economy to dismiss a count "which is capable of determination without the trial of the general issue," Fed. R. Crim. P. 12(b), because it would limit the number of people who would have to appear at Court. A pretrial motion under Rule 12(b) is appropriate under the circumstances.

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B. The Government's claims about the DSHEA lack necessary context and an analysis of both the statutory text and purpose of DSHEA clearly demonstrates that the government cannot prosecute Mr. Marschall for selling dietary supplements.

1. The Text, Purpose, and Applicability of the DSHEA

When interpreting a statute, the starting point is always the language of the statute itself. *Am. Tobacco Co. v. Patterson*, 456 U.S. 63, 68 (1982). Courts presume that Congress expressed its legislative intent through the ordinary meaning of the words it chose to use. *Perrin v. United States*, 444 U.S. 37, 42 (1979); *Richards v. United States*, 369 U.S. 1, 9 (1962). Legislative history may be a useful tool for statutory interpretation when it represents "the considered and collective understanding of those Congressmen involved in drafting and studying proposed legislation." *Zuber v. Allen*, 396 U.S. 168, 186 (1969).

a. Legislative findings of the DSHEA

The DSHEA created new rules for the regulation of dietary supplements. Pub. L. No. 103-417, 108 Stat. 4325 (1994).[1] The Congressional findings behind these rules are not only extensive but an integral part of the legislation. Pub. L. No. 103-417 at § 2, 108 Stat. at 4325. They speak in broad terms about the importance of dietary supplements for "health promotion" but also "disease prevention." Pub. L. No. 103-417 at § 2(2). They also speak to "a growing need for emphasis on the dissemination of information linking nutrition and long-term good health." *Id*. at §2(7). They created an affirmative right for individuals through "legislative action" that "protects the right of access of consumers to safe dietary supplements." *Id*. at §2(15)(A).

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[1] Exhibit 1 (DSHEA).

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b. Dietary supplements are defined as foods.

The DSHEA defined dietary supplements as foods. *Id.* at § 3(a), 108 Stat. at 4327-28 (codified at 21 U.S.C. § 321(ff)) Dietary ingredients are broadly defined. Pub. L. No. 103-417 at § 3(a) (codified at 21 U.S.C. § 321(ff)(1)).

The DSHEA also defined the form of ingestion of the dietary supplement. It required that a dietary supplement be intended for ingestion in one of many forms including a powder form. Pub. L. No. 103-417 at §3(c)(1) Finally, a dietary supplement must be labeled as such. 21 U.S.C. § 321(ff)(2)(C).

The undercover agent received the dietary supplements, Allimax Pro (Allimed) and IAG Arabinogalactans, in powder form and they were clearly labeled as such. The FDA recognizes them as foods. *See* 21 C.F.R. § 172.610 and 21 C.F.R. § 184.1317. The document that was sent along with these products to the agent is irrelevant in determining whether these two products are foods. In determining whether a product is a "food," under the DSHEA, "(t)he ordinary way in which an article is used…not any marketing claim on the part of the manufacturer or distributer as to specific physiological purpose of that use, should determine whether it is a food…" *United States v. Ten Cartons, Ener-B Nasal Gel*, 888 F. Supp. 381, 392 (E.D. New York, 1995) (citing *Am. Health Products Co., Inc. v. Hayes*, 574 F.Supp. 1498, 1505 (S.D. New York 1983).

c. The enforcement provisions of the DSHEA do not permit civil or criminal proceedings against Mr. Marschall because the government has not met the mandatory notice requirements.

The DSHEA also created enforcement provisions. Section 4 of the DSHEA preserves for dietary supplements those food adulteration standards that have been in the FDCA since 1906 and 1938. Pub. L. No. 103-417 at § 4, 108 Stat. at 4328 (codified at 21 U.S.C. § 342(f)(1)(D)). The enforcement provision provides two new adulteration standards to protect consumers from products that present a "significant or

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unreasonable risk of illness or injury" in two distinct scenarios: (1) under the "conditions of use recommended or suggested in labeling," Pub. L. No. 103-417 at § 4 (codified at 21 U.S.C. § 342(f)(1)(A)(i), and (2) where "no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use." Pub. L. No. 103-417 at § 4 (codified at 21 U.S.C. § 342(f)(1)(A)(ii)).

The DSHEA provides strict protocols before the FDA can initiate civil and criminal proceedings against an individual. When exercising this new authority in a civil proceeding, the FDA must first notify "the person against whom such proceeding would be initiated" and give that person the opportunity to present his or her views. Pub. L. No. 103-417 at § 4 (codified at 21 U.S.C. § 342(f)(2)). The notice must be given a least ten days prior to the reporting of any violation to a United States attorney. *Id*. This section is mandatory. The intent was to foreclose the FDA from exercising the discretion that allows the agency to forego such a hearing prior to reporting a criminal violation. *See generally United States v. Dotterweich*, 320 U.S. 277 (1943). The government has totally failed to adhere to these provisions because it did not provide Mr. Marschall with the mandatory notice to present his views, orally and in writing, at least ten days before reporting an alleged violation to a United States attorney.

In Mr. Marschall's motion (Dkt. 45 at 6), he argued that "(t)he indictment has totally failed to articulate how shipping Allimax Pro (Allimed) and IAG Arabainoglactans fails to adhere to 21 U.S.C. § 343(r)(6)(A) or 21 U.S.C. § 343–2(a)." Dkt. 45 at 6 (Motion to Dismiss). The government has failed to address this argument. *Justice v. Rockwell Collins, Inc*., 117 F. Supp. 3d 1119, 1134 (D. Or. 2015), *aff'd*, 720 F. App'x 365 (9th Cir. 2017) ("[I]f a party fails to counter an argument that the opposing party makes in a motion, the court may treat that argument as conceded").

As explained above, the DSHEA provides strict protocols before the FDA can initiate civil and criminal proceedings against an individual who sells a dietary

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supplement either as a wholesaler or a retailer. As the government's own cases demonstrate, it failed to adhere to them in this case because it never sent a notice or a letter to Mr. Marschall informing him that the claims he made about the Dynamic Duo turned the dietary supplements into drugs. *See Ten Cartons, Ener-B Nasal Gel,* 888 F. Supp. at 384-385 ("…the FDA notified Nature's Bounty that the FDA considered Ener–B to be a 'drug' under the FDCA, and that Ener–B was being marketed illegally because it had not received recognition or approval as a 'new drug' under the Act… Nature's Bounty responded to the FDA's letter, and on April 2, 1987 filed a Citizen Petition with the FDA…"); *See United States v. Lane Labs-USA, Inc.*, 427 F.3d 219, 221 (3rd Cir. 2005) ("At a convention in 1997, the Food and Drug Administration ("FDA") first observed Labs distributing materials promoting BeneFin to treat cancer. The FDA informed Labs through letters and telephone conversations that such conduct violates the FDCA."); *see United States v. Cole*, 84 F. Supp.3d 1159, 1163 (D. Or. 2015) ("On October 12, 2010, the FDA sent Defendants a letter warning them that their websites were making 'disease claims'—claims that their products could be used to diagnose, cure, mitigate, treat, or prevent a disease. By making such claims, the FDA warned, Maxam was selling unapproved new drugs."); *see United States v. Undetermined Quantities of Articles of Drug,* 145 F.Supp.2d 692, 697 (D. Md. 2001) (FDA provides "notice" announcing "its position that street drug alternatives constitute unapproved new drugs and misbranded drugs in violation of §§ 502 and 505 of the FDCA. 65 Fed.Reg. at 17.512," then seized "Defendants' products [because they] fall within the scope of the FDA's definition of street drug alternatives.").

The only case cited to by the government that involves a criminal prosecution is the misdemeanor unreported *Lebeau* case, which is truly an outlier in this type of litigation. *See United States v. Lebeau*, 2016 WL 447612 *1-2 (E.D. Wisconsin 2016) (describing convoluted litigation where defendant attempted to withdraw his guilty plea

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after admitting that he had in fact distributed a new drug into interstate commerce that had not been approved by the FDA). The product in question ("Perfect Colon Formula #1") was manufactured by defendant's company Vital Health Products, Ltd. and sold on its website. The only items Mr. Marschall sold for human consumption were both manufactured and bottled by entirely separate entities.

Further, the *Lebeau* case is distinct from the instant case because Mr. Lebeau pleaded guilty to the sale of an unapproved new drug before the appeal. The Seventh Circuit relied on that concession in its decision:

> Second, the court reasonably rejected LeBeau's belated assertion that he intended his product to treat only food "insensitivities," not "diseases." The assertion is contradicted by his concession to the government after it proffered its case at the plea colloquy. The proffer included the fact that LeBeau advertised that his product "reduces food allergies" and that this assertion was a "disease claim." LeBeau conceded that the proffer was "substantially correct."

See also LeBeau, 654 Fed. Appx. at 830.

d. DSHEA's Emergency Provisions

The DSHEA gives the government emergency authority to promptly declare that a dietary supplement poses an "imminent hazard to public health or safety." Pub. L. No. 103-417 at § 4 (codified at 21 U.S.C. § 342(f)(1)(C)). Section 4 also clarifies that the government, in all cases bears, "the burden of proof on each element to show that a dietary supplement" poses a threat to public safety and the court must decide the issue "on a de novo" basis based on evidence presented in court. Pub. L. No. 103-417 at § 4 (codified at 21 U.S.C. § 342(f)(1)).

The government has never claimed that the Dynamic Duo poses an imminent hazard to public health or safety. *See United States v. Nutri-cology*, 982 F.2d 394, 398 (9th Cir. 1992) ("Because the government failed to demonstrate *any* harm to consumers and because Nutri-cology submitted extensive evidence to the contrary, the district

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court did not abuse its discretion in finding that the government did not make the requisite showing of irreparable harm.") (emphasis in original); *Compare also* Dkt. 44-5 (Preliminary Hearing Transcript) (Q: Do the substances need to be illegal or do they need to be harmful to be considered drugs? A: No.) *with Ten Cartons, Ener-B Nasal Gel*, 888 F. Supp. at 392:

> The basic purpose of the DSHEA amendments to the FDCA is to ensure that the public has over-the-counter access to "dietary supplements," which include vitamins, minerals, amino acids and herbs. In order to accomplish this, the DSHEA precludes the FDA from regulating "dietary supplements" as a "drug" under section 321(g)(1)(C) solely because of any statements on the products' labelling regarding claims that the product can treat or affect a nutritional deficiency or disease, *unless the FDA determines that the product is not safe*.

Id. (emphasis added).

e. DSHEA's Labeling and Statement Provisions

The DSHEA altered and limited how the FDA defined "labeling" because, prior to the DSHEA, the definition of "labeling" created inconsistent and arbitrary legal results. *Compare United States v. Detroit Vital Foods*, 218 F.Supp. 208 (E.D. Mich. 1963) (FDA establishes literature is labeling) *with United States v. 24 Bottles ... Sterling Vinegar and Honey ...*, 338 F.2d 157 (2d Cir.1964) (FDA fails to establish literature is labeling). The DSHEA allows articles and publications to be used "in connection with the sale of a dietary supplement to consumers," Pub. L. No. 103-417, § 5, 108 Stat. at 4329 (codified at 21 U.S.C. § 403B(a)), provided that such information: is not false or misleading; does not promote a particular manufacturer or brand of dietary supplement; presents a balanced view of the available scientific information; if displayed in a store, is physically separate from the supplements; and does not have appended to it any information by sticker or other method. *Id.* (codified at 21 U.S.C. § 343-2(a)(1)-(5)). Moreover, in any action under this section, the government bears the burden of proof to

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"establish that an article or other information is false or misleading." *Id.* (codified at 21 U.S.C. § 343-2(c)). The section also preserves the right of retailers and wholesalers to carry and sell "books or other publications as a part of their business . . . ." *Id.* (codified at 21 U.S.C. § 343-2(b)).

The government has never claimed that Mr. Marschall's statements on the document that was sent with the Dynamic Duo or his statements on the phone are false or misleading. To the contrary, the government claims that it need not establish that "Mr. Marschall acted with the intent to defraud and mislead." Dkt. 22 at 8 (Government's Supplemental Preliminary Hearing Brief); *see also* Dkt. 38 (Indictment) (no allegation of intent to defraud or mislead).

The DSHEA states that dietary supplement vendors can make statements describing how consumption of the supplements affects structure or function in humans, or their general well-being. Pub. L. No. 103-417 at § 6, 108 Stat. at 4329 (codified at 21 U.S.C. § 321(ff)). The right to make such statements applies to all dietary ingredients as defined in the new dietary supplement definition. Pub. L. No. 103-417, § 6, 108 Stat. at 4329 (codified at 21 U.S.C. § 321(ff)). Such a statement may: claim a benefit related to a classical nutrient deficiency disease if it discloses the prevalence of such disease in the United States; describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans; characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or; describe general well-being from consumption of a nutrient or dietary ingredient. *Id.* (codified at 21 U.S.C. § 343(r)(6)(A)). Mr. Marschall's statements regarding the consumption of the Dynamic Duo, along with any allegation that he is making statements regarding how the Dynamic Duo affects functions in humans or their general well-being, is protected under this provision.

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This section does not allow a manufacturer to make a drug claim for a product, i.e., a statement claiming to "diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases." *Id.* (codified at 21 U.S.C. § 343(r)(6)); *see also* 21 U.S.C. § 321(g)(1)(B). Conversely, a dietary supplement may not be deemed a drug solely because it includes such a statement. Pub. L. No. 103-417 at § 10, 108 Stat. at 4332 (amending 21 U.S.C. § 321(g)(1)). To emphasize that statements of nutritional support are not drug claims, the Act requires that any statement of nutritional support made under this section contain (prominently and in boldface type) the following disclaimer: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." Pub. L. No. 103-417 at § 6, 108 Stat. at 4329 (codified at 21 U.S.C. § 343(r)(6)(C)). The government has never claimed that Mr. Marschall did not provide adequate disclaimers. Even if the FDA believes that a drug claim is made about the Dynamic Duo, notwithstanding a disclaimer, criminal prosecution cannot be initiated unless the FDA complies with the enforcement procedures under DSHEA. *See* 21 U.S.C. § 342(f)(2). This section, again, is mandatory. If the FDA believes that there are emergency circumstances, it can initiate proceedings claiming that the product "pose[s] an imminent hazard to public health or safety." *See* 21 U.S.C. § 342(f)(1)(C). No such declaration has ever been made or implied in the multiple proceedings that have taken place in this case or in government filings.

The FDA is not claiming that Mr. Marschall introduced a new drug because, as Mr. Marschall has established (and the government has never disputed), Allimax Pro (Allimed) and IAG Arabinogalactans are both foods that have been deemed safe for human consumption by the FDA. *See* 21 C.F.R. § 172.610 and 21 C.F.R. § 184.1317. The FDA has published a study proclaiming the health benefits of garlic and its derivatives, i.e., Allimax Pro (Allimed). The FDA makes available, on its own website,

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a study prepared for the agency in 1973 describing the health benefits associated with the consumption of garlic and its extracts. Evaluation of the Health Aspects of Garlic and Oil of Garlic as Food Ingredients, February 1973, Bureau of Foods, FDA. Available at https://ntrl.ntis.gov/NTRL/dashboard/searchResults.xhtml?searchQuery=PB223838; *See King v. Cty. of L.A.*, 885 F.3d 548, 555 (9th Cir. 2018) ("(W)e take judicial notice of the undisputed and publicly available information displayed on government websites."). In that report, the following claims were made with respect to respiratory and blood based illnesses:

> In an investigation of the effects of garlic powder in controlling infectious chronic lung congestion. It was noted that Wistar rats on a 2.5 percent dehydrated garlic diet, equivalent to 10 percent fresh garlic, showed a slight lowering of the hemoglobin concentration and red cell count (23). On a diet of 5 percent dehydrated garlic, equivalent to 20 percent fresh garlic, the second generation rats were sterile.
>
> A decrease in blood pressure was observed both in the first five minutes and in the following hour when rabbits were given 0.015 mg per kg of "garlic juice" (24). The pressure gradually returned to its original level after two hours. No side effects were noted. When garlic juice, obtained by pressing, was administered orally to guinea pigs at a level of 1 cc per kg body weight daily, the blood calcium level increased to a peak between 14 and 28 days, but became normal again after 2 months of the same diet (25). A comparable reaction has also been reported in dogs (26)… Inhalation of garlic juice diluted in physiological salt solution 0 r with 0.25 percent of a 1:3 procaine solution by 34 patients with chronic pneumonia complicated by candidiasis of the lungs brought out an improvement in 26 of the patients (31). There was a decrease or disappearance of the candida fungus from the sputum of 16 patients.

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Id. at 5-6 (attached as Exhibit 3). That study, along with all the studies that speak to the health benefits of both these products, have never been disputed by the government. *See* Dkt. 19-3 (Published Studies).[2]

It is important to emphasize that a representative of the FDA testified, under oath, that the agency would prosecute a private citizen for sending garlic to a family member to cure a cold. Dkt. 44-5 at 54 (Prelim. Hearing Transcript). Facts, such as that, exemplify how dangerous the government's interpretation of the statute is in this case.

DATED this 9th day of October 2020.

Respectfully submitted,

s/ *Mohammad Hamoudi*
s/ *Gregory Geist*
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[2] These same studies have been provided to the Court in Mr. Marschall's reply motion to dismiss the indictment on First Amendment grounds.

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